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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/362,598	07/28/1999	JOEL V. WEINSTOCK	3948/79934	7062

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EXAMINER

ZEMAN, ROBERT A

ART UNIT PAPER NUMBER

1645

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/362,598

Applicant(s)

WEINSTOCK ET AL.

Examiner

Robert A. Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24,26 and 28-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24,26 and 28-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 3-25-2005 has been entered.

The amendment and response filed on 12-9-2004 is acknowledged. Claims 24, 26 and 32 have been amended. Claims 24, 26 and 28-32 are pending and currently under examination.

The Declaration by Drs. Joel V. Weinstock and David E. Elliot filed on 12-9-2004 is acknowledged and has been fully considered.

Claim Rejections Withdrawn

The rejection of claims 24, 26 and 28-32 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an *in vitro* method of determining the immune response the co-infection of mice with *M. avium* and *S. mansoni* (either with or without TNBS treatment) or the infection of mice with *T. muris* (with TNBS treatment) by determining the amounts of IL-4, IL-5 and IFN-K, does not reasonably provide enablement for a method of screening an helminthic parasite preparation for one or more components that reduce excessive Th1 immune responses, wherein said preparation is prepared by fractionating and sub-fractionating the helminthic preparation is withdrawn. Applicant's arguments have been fully considered and deemed persuasive.

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The rejection of claims 24, 26 and 28-32 under 35 U.S.C. 103(a) as being unpatentable over Pearce et al. (Journal of Exp. Medicine, Vol.173, pages 159-166, 1991) in view of Pearce et al. (PNAS, Vol. 85, pages 5678-5682, 1988) is withdrawn in light of the amendment thereto. The cited references either alone or in combination do not render obvious the steps of sub-fractionating and testing the resulting products.

The rejection of claim 32 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. is withdrawn in light of the amendment thereto.

New Grounds of Rejection

35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Said claim is rendered vague and indefinite by the use of the phrase “as evidenced by an *in vitro* assay”. It is unclear what is what limitation is meant to be conferred by the term “evidenced” nor is it clear to what “assays” Applicant is referring. Consequently, it is impossible to determine the metes and bounds of the rejected claim.

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The instant claims are drawn to a method of screening a helminthic preparation for one or more components that reduce a Th1 immune response. The method comprises preparing and fractionating and sub-fractionating the preparation and assaying the products for the ability to reduce a Th1 immune response.

Claims 24, 26 and 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kullberg et al. (Journal of Immunology, 1992, Vol. 148, No. 10, pages 3264-3270 -- IDS).

Kullberg et al. disclose the helminthic parasite *Schistosoma mansoni* down regulates the Th1 cytokine secretion of IL-2 and IFN- γ in mice (see abstract). Kullberg et al. further disclose

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that Th1 responses were determined by cytokine profiles as measured by *in vitro* ELISA assays (see materials and methods and results sections). Kullberg et al. differs from the instant invention in that they don't disclose the method steps of fractionating, sub-fractionating and testing of the sub-fractionates. However, as attested to by Drs. Weinstock and Elliot in their Declaration filed under 37 C.F.R 1.132 on 12-9-2005: "fractionation and testing of resulting fractions and sub-fractions for activity, as claimed, is a well-known and routine method for isolating the biologically active component(s) of a complex biological mixture. It is also well known in the art that the same assay can be used at each stage of a fractionation procedure to monitor which fraction(s) or sub-fraction(s) have the activity of interest" (see point 4 of Declaration). Consequently, it would have been obvious for one of ordinary skill in the art to use these "well known and routine methods" to identify the component(s) of the parasite composition responsible for the down regulation of Th1 cytokine secretion. One would have been motivated to identify said component(s) in order to produce a "pure" composition capable of reducing a Th1 response without the possible negative effects of caused by the other constituents of the nematode composition. One would have had a reasonable expectation of success since said methods are well known and routine in the art.

Claims 24, 26 and 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (WO 96/29802 – IDS).

Lee et al. disclose the down regulation of Th1 activity in mice can be accomplished by the administration of soluble helminthic nematode extract (see page 5, line 21 to page 6, line 4 and page 10)). Lee et al. further disclose that Th1 responses were determined by cytokine profiles as measured by *in vitro* ELISA assays (see Example 2). Lee et al. differs from the instant invention in that it does not explicitly disclose the method steps of fractionating, sub-fractionating and testing of the sub-fractionates. However, as attested to by Drs. Weinstock and Elliot in their Declaration filed under 37 C.F.R 1.132 on 12-9-2005: "fractionation and testing of resulting fractions and sub-fractions for activity, as claimed, is a well-known and routine method for isolating the biologically active component(s) of a complex biological mixture. It is also well known in the art that the same assay can be used at each stage of a fractionation procedure to monitor which fraction(s) or sub-fraction(s) have the activity of interest" (see point 4 of Declaration). Consequently, it would have been obvious for one of ordinary skill in the art to use these "well known and routine methods" to identify the component(s) of the parasite composition responsible for the down regulation of Th1 cytokine secretion. One would have been motivated to identify said component(s) in order to produce a "pure" composition capable of reducing a Th1 response without the possible negative effects of caused by the other constituents of the nematode composition. One would have had a reasonable expectation of success since said methods are well known and routine in the art.

Conclusion

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert A. Zeman

June 13, 2005